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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,552	07/06/2001	Lauraine Wagter-Lesperance	6580-239	7030

7590

06/30/2005

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EXAMINER
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NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/899,552

**Applicant(s)**

WAGTER-LESPERANCE ET AL.

**Examiner**

Patrick J. Nolan

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 25-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11-5-01.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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1. Claims 1-38 are pending.
2. Applicant's election with traverse of Group I, claims 1-24 in the reply filed on 4-22-05 is acknowledged. The traversal is on the ground(s) that an art search for Group I would necessarily uncover art for the Group II. This is not found persuasive because as is readily disclosed in the IDS references applicant has submitted 11-5-01, there are many examples of prior art where animals were tested for antibody response to rank immune responders without being concomitantly being tested for cell mediated immune responses, so a prior art search for antibody responses to rank immune responder would not uncover all art pertaining to ranking immune responders by cell mediated immunity.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 25-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4-25-02.
4. Applicant is advised that should claim 1 be found allowable, claim 2 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
5. Claim 11 is objected to because of the following informalities: there is no SEQ ID NO, for the sequence tyrosine-glutamine-alanine-lysine. In addition, glycine should be replaced with glutamine. Appropriate correction is required.
6. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The term restraint in claim 6 has no support in the originally filed specification. Furthermore, in claims 4 and 5 the coefficient multiplication of 1 or 1.5 is

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presently only disclosed for those rankings where a primary and secondary response calculation has occurred.

7. It is noted that for claims 4 and 5, the effective filing date is limited to the disclosure of the instant application. So, for prior art purposes the date of invention for claims 4 and 5 is 7-6-01.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 6-19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagter et al. (J. Dairy Science, 1996, Vol. 79(Suppl 1), page 119, reference 25 in the IDS submitted 11-5-01).

Wagter et al., discloses ranking antibody immune responses in 32 perparturient cows and heifers vaccinated with ovalbumin and the E.coli J5 vaccine at -8 and -3 weeks before calving and at calving and antibody responses were determined at -3, 0, 3 and 6 weeks relative to calving. High immune responders were ranked based upon phenotypic observations of antibody response curves kinetics to OVA.

It is noted that claims 9, 10 and 16 are included because pregnant cows are either multiparous or primiparous and it is standard in farm animals to test for antibody responses from easily obtainable sources, milk or blood. Applicant is invited to disclose what the makeup of the cows were and where they obtained the source for antibody determination as disclosed at the meeting in the poster presentation to discern whether applicant publicly disclosed such information more than one year to filing in what is considered a printed publication. See *In re Klopfenstein*, 72 USPQ2d 1117 (CA FC 2004). Furthermore, claim 13 is included in the rejection because it is noted that the vaccine formulation E.coli J5 has a commercial adjuvant

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within it, that from the Examiners searching appears to be mycobacterium toxoid protein from the cell wall. Applicant is requested to clarify the composition of the commercially obtained vaccine. Claim 21 has been included in the rejection because the abstract discloses antibody curve kinetics to ova were generated and animals were ranked accordingly. It is common practice to use statistical analysis to determine significance of experimental results. The Examiner is requesting the full results displayed at the meeting so a proper determination of prior art can be made.

The prior art teachings anticipate the claimed invention.

10. Claims 4 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by CA 2,255,423, publication date of 6-10-00.

The '423 patent application teaches ranking an immune response of a test animal by immunizing the animals with at least one antigen at least once before the onset of stress and at least once during the stress measuring the antibody response of the animals to the at least one antigen at least once before the stress and at least twice during the stress and providing a total antibody response by adding the antibody responses for each measurement and wherein when the test animal total antibody response is higher than the average, classifying the animal as a high immune responder. In addition the reference teaches multiplying the negative changes in antibody changes during the stress with a co-efficient of about 1.5 (see page 19-20 in particular).

The claimed invention is anticipated by the prior art.

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-3, 6-12, 14-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,287,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are species claims to the instantly filed claims except for some of the times of measurement and what the negative antibody responses during stress are multiplied by. However these limitations are clearly preferred embodiments as disclosed in the specification of the '564 patent and therefore would be obvious in light of the claims.

13. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

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Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

June 24, 2005